**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF TEXAS**
**HOUSTON DIVISION**

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| GIOVANNA BULOX,<br>MATIAS BULOX,<br>LORENA AHIRI MERLO, and<br>DANIEL MERLO | § | |
| *Plaintiffs* | § | Case No. 4:21-cv-2320 |
| v. | § | |
| COOPERSURGICAL, INC.,<br>FEMCARE, LTD. – UK SUBSIDIARY OF<br>UTAH MEDICAL PRODUCTS, INC., and<br>UTAH MEDICAL PRODUCTS, INC. | § | |
| *Defendants* | § | |

**PLAINTIFFS' OBJECTIONS TO MAGISTRATE JUDGE'S REPORT AND RECOMMENDATION**

COME NOW Plaintiffs, Giovanna Bulox, Matias Bulox, Lorena Merlo, and Daniel Merlo (hereinafter "Plaintiffs") by and through their counsel Griffin Purnell, LLC and hereby submit their objections to Magistrate Judge Palermo's Report and Recommendation dated March 6, 2025 (Dkt. #190), which recommends granting the motions for summary judgment filed by Femcare, Ltd. (hereinafter "Femcare") and Utah Medical Products, Inc. ("Utah Medical") (Dkt. #123 and #125), and the joinder to Femcare's motion for summary judgment filed by CooperSurgical, Inc. (hereinafter "CooperSurgical") (Dkt. #124) on preemption grounds. For the reasons set forth below, Plaintiffs respectfully request that this Court reject the Magistrate Judge's recommendations and deny Defendants' motions for summary judgment.

## I. INTRODUCTION

This case presents the scenario where patients were injured by a medical device whose manufacturer is alleged to have concealed critical safety information from the FDA, the medical

community, and the patients who were ultimately implanted with these devices. Plaintiffs filed this case after Giovanna Bulox and Lorena Merlo were each injured after Filshie Clips, a medical device with which both women were implanted during their respective tubal ligation procedures, migrated from the original implantation site. Defendants Femcare, Utah Medical, and CooperSurgical filed motions for summary judgment arguing that Plaintiffs' claims are preempted by the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). (Dkt.#123, #124, #125).

On July 18, 2024, this case was transferred to Magistrate Judge Palermo for all pretrial purposes. (Dkt. #173). Magistrate Judge Palermo recently issued a Report and Recommendation (hereinafter "Report") regarding the pending motions for summary judgment. (Dkt. #190). The Report concludes that federal preemption bars Plaintiffs' state law claims. In reaching this conclusion, the Report misapplies the preemption jurisprudence and overlooks key case law that permits Plaintiffs' parallel state law claims to proceed in this Court.

The Report specifically fails in applying preemption law to the design defect and failure-to-warn claims alleged by Plaintiffs. The Report also fails to address several arguments made by Plaintiffs in the briefing that demonstrate the viability of these claims. These errors warrant a rejection of the Report and Recommendation.

## II. LEGAL STANDARD

This Court reviews de novo those portions of the Magistrate Judge's Report and Recommendation to which timely objections have been made. 28 U.S.C. § 636(b)(1)(C); Fed. R. Civ. P. 72(b)(3). Objections to the Recommendation of a Magistrate Judge must be made within 14 days of being served with a copy of the recommended disposition. Fed. R. Civ. P. 72(b)(2). Judge Palermo's Report and Recommendation was filed on March 6, 2025 and specifically notes

the fourteen-day time period for party Objections. (Dkt. #190, at p.18). When considering the Magistrate Judge's recommendations, the Court "may accept, reject, or modify the recommended disposition; receive further evidence; or return the matter to the magistrate judge with instructions." Fed. R. Civ. P. 72(b)(3). Texas District Court judges have declined to adopt the report and recommendations entered by the Magistrate Judge. *See Williams v. Collins,* 802 F. Supp. 1530, 1532 (W.D. Tex. 1992), *C2 Assocs. Bus. Strategy & Dev., LLC v. L3Harris Techs. Integrated Sys. L.P.,* No. 6:23-CV-00762-ADA, 2025 U. S. Dist. LEXIS 23023, at *2 (W.D. Tex. Feb. 10, 2025) (rejecting the Magistrate's recommendation in part).

## III. OBJECTIONS AND AUTHORITY

### A. The Law Governing Express and Implied Preemption

Defendants argue that Plaintiffs' state law claims are preempted by the MDA. (Dkt. #123, #124, #125). The MDA was enacted in 1976 to give consumers greater protection from medical devices manufactured and marketed by companies like Defendants. 21 U.S.C. § 360c *et seq*. Congress passed the MDA at a time of public outcry for greater regulation in the wake of medical device failures. S. Rep. No. 94-33, at 6 (1975); 121 Cong. Rec. 10688 (1975). The preamble to the MDA states that it was enacted to "provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539.

In *Riegel v. Medtronic, Inc.*, the Supreme Court held that a claim based on a Class III medical device is *expressly* preempted by the MDA if the state common law claims impose requirements that are "different from, or in addition to" those imposed by federal law. 552 U.S. 312, 321-22 (2008) (quoting 21 U.S.C. § 360k(a)(1)). The express preemption provision "does not[, however,] prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal

requirements." *Id*. at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). Congress did not intend for the MDA to have a "perverse effect of granting complete immunity from [tort] liability to an entire industry that, in the judgment of Congress, needs more stringent regulation in order to provide for the safety and effectiveness of medical devices intended for human use.'" *Lohr*, 518 U.S. at 487.

Section 337 of the MDA requires that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337a. The Supreme Court interpreted this to mean that state law claims were *impliedly* preempted if those claims seek to privately enforce a duty owed to the FDA. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001). When giving its ruling, the *Buckman* court focused on the fact that the lawsuit at issue did not invoke any breach of duty owed to the plaintiff, but was "solely from the violation of the FDCA requirements." *Id.* at 352-53. However, a claim that merely uses relevant federal regulations as the measure of the standard of care required by the defendant to fulfill a duty owed under traditional state tort-law principles survives preemption.

In short, to survive preemption, Plaintiffs' state law claim must fit in a "narrow gap" by alleging conduct violates FDA regulations (to escape express preemption), but that the suit is not brought *because* of the violation of FDA regulations (to avoid implied preemption). *In re Medtronic, Inc., Sprint Fidelis Leads*, 623 F.3d 1200, 1204 (8th Cir. 2010). In the instant case, Plaintiffs have carefully plead state law claims allegations allege FDA violations as well as parallel state law duties. As such, their claims fit through the "narrow gap" and present viable state law causes of action that are not subject to preemption.

**B. Plaintiffs' Design Defect Are Not Preempted**

Initially, the Report concludes that Plaintiffs' design defect claims are preempted because

they "have not alleged that the product in question was designed in violation of federal standards." (Dkt. #190 at p. 8). This conclusion mischaracterizes Plaintiffs' claims and overlooks the connection between Defendants' reporting violations and the continued use of a defective design.

Plaintiffs' design defect claims specifically allege that "[t]he design was approved by the FDA without the benefit of the knowledge that Filshie Clips had a greater than .13% risk of migration . . . Such failure [to report] allowed for the defective design to remain the same." (Dkt. #40 at ¶ 71). This allegation establishes a causal connection between Defendants' violation of federal reporting requirements and the continued marketing of a defectively designed product.

The Filshie Clip has been classified as a Class III under the MDA as it *inter alia* "presents a potential unreasonable risk of illness or injury." *Riegel*, 552 U.S. at 317 (citing 21 U.S.C. 360c(a)(1)(C)(ii)). Thus, the "unreasonably dangerous" portion of Texas product liability law parallels the "unreasonable risk of illness and injury" definition of Class III medical devices under the federal requirements. To avoid preemption under the MDA, a federal regulation does not need be identical to, or have the exact same terms as, a state law claim. Rather, a state common law claim is preempted if it imposes *requirements* that are "different from, or in addition to" those imposed by federal law. 21 U.S.C. § 360k(a)(1). Texas product liability law or Section 402A does not impose any additional requirements to those imposed by the MDA – both require parallel duties to ensure that Defendants products are safe for use.

The Magistrate's Report and Recommendations relating to Plaintiff's design defect claim largely ignores the similar product liability claims brought under Texas State Law that survived preemption challenges. *See e.g. Purcel v. Advanced Bionics Corp*, 2010 WL 2679988, at *6 (N.D. Tex. June 30, 2010) (ruling in favor of plaintiff in summary judgment motions as claims for "negligent failure to follow federal law," fraud, negligent misrepresentation, and breach of

warranty are not preempted); *Hardy v. Zimmer*, 2017 WL 1551601, at *3 (E.D. Tex. Apr. 28, 2017) (denying defendant's motion for summary judgment as claims based on nondisclosure may contain factual theory that would not be preempted); *Zappe v. Medtronic USA, Inc.*, 2009 WL 10694308, at *1 (S.D. Tex. Aug. 18, 2009) (denying defendant's motion for summary judgment allowing plaintiff's strict liability and negligence claims to proceed at this stage in the litigation); *Goodwin v. Medtronic, Inc.*, 2021 WL 7448501, at *4 (E.D. Tex. June 4, 2001) (strict liability and manufacturing defect claims not preempted because they rest on alleged violations of federal requirements; following *Hughes* ruling).

The Report also concludes that, in the alternative, even if Plaintiffs' design defect claims were not preempted, the proposed alternatives to Filshie Clips are not considered "safer and feasible" design alternatives under Texas Law. (Dkt. #190 at p. 10). Instead, the Magistrate found that the proposed alternatives, which include cauterization of the fallopian tubes during a tubal ligation or a salpingectomy or complete removal of the tubes, were actually different strategies entirely. (*Id.*). In drawing this conclusion, however, the Report construes the concept of "design alternatives" very narrowly and ignores several safer alternative methods for performing bilateral tubal ligations outlined in Plaintiffs' briefing. (*See* Dkt.#137, p. 13). Tubal cauterization, for instance, is unquestionably an alternative to the use of Filshie Clips during a tubal ligation. Another alternative, a salpingectomy procedure, has been available "forever" and is feasible and cost-effective. (Dkt. #137, p. 13-14). These procedures, though rejected by the Report without analysis, represent safer alternatives to tubal ligations using Filshie Clips.

### B. The Magistrate's Report and Recommendation Misapplies Preemption Jurisprudence to Plaintiffs' Failure-to-Warn Claims

Next, the Report also finds that Plaintiffs' failure-to-warn claims are preempted by federal law. Plaintiffs base their failure to warn claim on the "later-acquired knowledge" theory addressed

by the Report. (Dkt. #190, p.12-13). Ultimately, Plaintiffs contend that Defendants failed to provide required information to the FDA, including: adverse event reports, relevant journals and articles discussing high migration rates, and migration data. (Dkt. #137).

1. **There is a Parallel Duty Under Texas Law**

The Report concludes that Plaintiffs' failure-to-warn claims are impliedly preempted because there is no duty under Texas law that parallels the FDA reporting requirements. (Dkt. #190, p. 13). In reaching this conclusion, the Report largely ignores the argument and legal analysis detailed in Plaintiffs' brief in Response to Femcare's Motion for Summary Judgment. (Dkt.#137). Plaintiffs have demonstrated that there *is*, in fact, a parallel state law duty to report adverse events in Texas.

Under Texas law, "[l]iability for failure to warn is imposed where a manufacturer does not exercise *reasonable care in . . . warning of a given danger*." *Romero v. Wyeth LLC*, 2012 WL 12547105, at *4 (E.D. Tex. May 30, 2012) (emphasis added). The Supreme Court of Texas has held that, in certain scenarios, defendant's duty to warn is discharged by providing information about the product's dangerous propensities to a third person whom it can reasonably rely on to communicate the information to the ultimate users of the product. *Alm v. Aluminum Co.*, 717 S.W. 2d 588, 591 (Tex. 1986). This doctrine is based on Restatement (Second) Torts at § 388 cmt. n and Restatement (Third) Torts at § 2(c) cmt. i, both of which have been adopted by Texas courts. *Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 186-90 (Tex. 2004).

Courts around the country have similarly concluded that this duty to warn "a third person", as set forth under the Restatement, constitutes a duty parallel to the duty to report to the FDA.[1]

[1] *See e.*g. *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Penn. 2016) (denying a motion to dismiss because Pennsylvania adopted Section 388, which imposes a duty to file adverse reports to the FDA); *In re Allergan Biocell Textured Breast Implant Prod. Liab. Lit.*, 537 F. Supp. 3d 679, 711 (D.N.J. 2021) (failure to warn claims are neither expressly nor impliedly preempted as under the Restatement (Second) of Torts § 388 and it is the

Generally these courts rely on the Fifth Circuit's opinion in *Hughes* v. *Boston Scientific Corp.,* which is discussed in further detail in a later section of this brief, and "identif[y]" these Restatement sections as a "[state] law that imposed [a] duty" on the manufacturer to report adverse events to the FDA. *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Penn. 2016) (denying a motion to dismiss because Pennsylvania adopted Section 388, which imposes a duty to file adverse reports to the FDA). As a result, these courts have found that a plaintiff's failure to warn claims that are based on a failure to adhere to FDA reporting requirements are not preempted by the MDA.[2] Texas courts have adopted the very same Restatement sections that have been recognized as imposing a duty on defendants to report adverse events.

Texas law requires manufacturers to exercise *reasonable care* in warning of the dangers associated with their products. In instances where the product in question is a medical device regulated by the FDA, the most reasonable and practical method a manufacturer can use to warn of these risks is through the FDA. The FDA, in turn, can guide the manufacturer through the process of corrective action, including revising IFUs, marketing materials, product warnings, issuing recalls, etc. Because FDA reporting is logistically necessary in order for a medical device manufacturer to fulfil its duty to warn under Texas law, the duties and requirements imposed on manufacturers of medical devices by federal law and Texas product liability law are parallel.

**2. The 5th Circuit's opinion in *Hughes* is Relevant and Necessary to Preemption Analysis under Texas Products Liability Law**

The Report largely ignores or discounts the Fifth Circuit opinion in *Hughes v. Boston*

manufacturer's duty to report to the FDA); *Richardson v. Bayer Healthcare Pharm. Inc.*, 2016 WL 4546369, at *8 (D. Idaho Aug. 30, 2016) (failure to warn claims not impliedly preempted as "Plaintiff's report-based failure to warn claims are based on state law tort principles illustrated in § 388 of the Restatement (Second) of Torts, and not solely based on [Defendant's] alleged fraud on the FDA"); *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343, 362 (D. Del. 2019) (finding that failure-to-warn claims based on Restatement (Second) of Torts § 388 survives express and implied preemption if properly pled).

[2] *See* previous footnote.

*Scientific Corp.*. The Report concludes that the *Hughes* case is "distinguishable" because the opinion concerns a "now defunct Mississippi products liability law." 631 F.3d 769 (5th Cir. 2011); (Dkt. #190 at p. 15). Despite the Report's findings to the contrary, the Fifth Circuit's decision in *Hughes* is highly relevant and instructive to the preemption inquiry in this case.

In *Hughes*, the plaintiff's main cause of action was based on defendant's failure to adhere to the FDA's medical device reporting requirements by under-reporting adverse events (deaths or serious injuries) caused by the device. 631 F.3d at 769. The court determined that the duty to provide adequate warnings under Mississippi state law "has been construed by Mississippi courts as a duty to provide 'reasonable warnings' of risks." 631 F.3d at 769 (internal citations omitted). The Fifth Circuit held that a state law failure to warn claim predicated on the defendant's failure to "provide adequate warnings or sufficiently communicate information about the risk associated with the device" was not preempted "to the extent that the claim is predicated on [defendant's] failure to report 'serious injuries and malfunctions of the device as required by the applicable FDA regulations." *Id* at 769. District courts in Texas use the *Hughes* ruling as guidance when determining preemption. *See e.g. Briggs v. Endologix, Inc.*, 2023 WL 2716592 (S.D. Tex. Mar. 30, 2023) In *Briggs v. Endologix, Inc.,* the Southern District of Texas recognized the *Hughes* standard when analyzing failure-to-warn claims plead under Texas law, even though it ultimately held that Plaintiff's claims were preempted for failing to set forth an applicable FDA regulation. *Id.*

While the *Hughes* court did address claims brought under a previous Mississippi state law, attempts to distinguish the holding's applicability to the instant case are unpersuasive. The *Hughes* court analyzed a Mississippi state law that imposed a duty on manufacturers to provide "reasonable warnings of risks". 631 F.3d at 769. Significantly, this is the same requirement Texas statutes

impose upon a manufacturer in the context of a failure to warn claim.[3] Consequently, the reasoning and analysis set forth in the *Hughes* opinion is instructive and applicable to this Court's preemption inquiry regarding Ms. Bulox and Ms. Merlo's failure to warn claims.

The fact that the Report and Recommendations largely ignored the *Hughes* decision constitutes significant error. While the Fifth Circuit's interpretation of Mississippi law may not technically be binding on this Court, the *Hughes* decision has had a profound effect on preemption analysis in failure to warn cases plead under state laws around the country. Numerous courts have relied *inter alia* on the *Hughes* case when conducting a preemption analysis related to claims plead under the laws of states other than Mississippi, including but not limited to: Massachusetts, Maryland, Illinois, Washington, D.C., New York, California, Hawaii, Indiana, Louisiana, Vermont, Pennsylvania, New Jersey, Delaware, and Texas.[4] For all of these reasons, the *Hughes* rationale, which supports the viability of Ms. Bulox and Ms. Merlo's failure to warn claims, is relevant and necessary to the Court's preemption inquiry.

[3] As discussed in the previous subsection.

[4] *Plourde v. Sorin Group USA, Inc.*, 2018 WL 1542361, at *7 (D. Mass. Mar. 29, 2018) (concurring "with the many federal district courts which have deterred that a state-law claim for failure to report information to the FDA is not preempted" (under Massachusetts law)); *Williams v. Smith & Nephew*, 123 F. Supp. 3d 733, 742-43 (D. Md. 2015) (Maryland recognizes a state law duty to report adverse events to the FDA, therefore, such claims are not preempted by the MDA); *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026, 1033 (N.D. Ill. 2016) (same based on Illinois law); *Kubicki ex refl. Kubicki v. Medtronic*, 2013 WL 1739580, at *6-9 (D.C.C. Mar. 21, 2013) (same based on DC law); *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170 (N.D.N.Y. 2014) (same based on New York law); *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413 (2014) (same based on California law); *Beavers-Gabriel v. Medtronic, Inc.*, 2015 WL 143944, at *12 (D. Haw. Jan. 9, 2015) (same based on Hawaii law); *McAfee v. Medtronic, Inc.*, 2015 WL 3617755, at *5 (N.D. Ind. 2015) (same based on Indiana law); *Gavin v. Medtronic, Inc.*, 2013 WL 3791612, at *14 (E.D. La. July 19, 2013) (same based on Louisiana law); *Halsey v. Smith & Nephew*, 2014 WL 12717702, at *10-11 (D. Vt. Feb. 4, 2014) (same based on Vermont law); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838 (E.D. Penn. 2016) (same based on Pennsylvania law); *In re Allergan Biocell Textured Breast Implant Prod. Liab. Lit.*, 537 F. Supp. 3d 679, 711 (D.N.J. 2021) (same based on New Jersey law); *Freed v. St. Jude Med., Inc.*, 364 F. Supp. 3d 343, 362 (D. Del. 2019) (same based on Delaware law).

**3. The Report Fails to Address the *Schouest* Case, which is Relevant and Instructive to the Instant Preemption Inquiry**

The Report fails to address the Southern District of Texas case, *Schouest v. Medtronic*, which is cited heavily by Plaintiffs in their briefing (Dkt.#137, p. 9-12). 13 F. Supp. 3d 692 (S.D. Tex. 2014). The *Schouest* court found that plaintiff's claims based on withholding information from the FDA during the premarket approval process is "fraud-on-the-FDA" claim and, therefore, preempted. *Id.* at 705-06. Notably, however, the *Schouest* court followed the rationale of the *Hughes* opinion and found that Plaintiffs' claims are not preempted where the Plaintiff can identify a state law duty to report adverse events and identify which FDA reporting regulations were violated by Defendants. *Id.* at 706 (citing *Thomas v. Hoffman-LaRoche, Inc.* 949 F.2d 806, 811 (5th Cir. 1992) ("Mississippi law requires a manufacturer to give a reasonable warning warning")). The *Schouest* court explained its reasoning as follows:

> [Such] claim also involve one exception to the Court's general holding that claims premised on a failure to do something are either expressly or impliedly preempted: [an action] predicated on [defendant's] failure to submit adverse-event reports to the FDA after the FDA granted the [device] premarket approval. Indeed, the Fifth Circuit directly held in *Hughes* that such a claim could survive . . . This particular claim survived in *Hughes* because the defendants had an independent duty under Mississippi law to warn about the dangers or risks of the product. The court determined that because the plaintiff was asserting a recognized state tort claim through an FDA violation, her claim survived *Buckman*. So to the extent [plaintiff] can point to a state law duty to report adverse events, and critically, what FDA reporting regulations [defendants] allegedly violated, this claim could escape preemption.

*Id.*

In this case, Ms. Bulox and Ms. Merlo have satisfied both requirements of *Schouest.* As Plaintiffs' have demonstrated in this Objection as well as in their previous briefing in Opposition to Defendants' motions for summary judgment, Texas imposes a state law duty on manufacturers of medical devices to report adverse events to the FDA. Plaintiffs have also met their burden in

demonstrating the manners in which Defendants breached their duty to report these adverse events to the FDA. (Dkt.#137).

First, as discussed more fully in an earlier section of this brief, when a products liability claim involves a medical device, Texas law imposes a duty to report to the FDA. Texas law requires manufacturers to exercise "reasonable care" in warning of a danger. *Romero*, 2012 WL 12547105, at *4). As a practical matter, a medical device manufacturer would have to involve the FDA in any process required to warn of the dangers of its device. Additionally, the duty imposed by Texas law is nearly identical to the Mississippi law interpreted by the *Hughes* court as imposing the duty to report adverse events to the FDA. 631 F.3d at 769.

Next, Plaintiffs have demonstrated that FDA reporting regulations were violated by Defendants to satisfy the second *Schouest* requirement. 13 F. Supp. 3d at 706. The factual record demonstrates genuine issues of material fact regarding whether Defendants violated FDA regulations by failing to report adverse events and withholding critical information about the true migration rate of Filshie Clips. FDA. 21 C.F.R. § 814.84 *et seq*., 803.10, 803.40, 803.50, 803.58. Plaintiffs allege that the following conduct:

1. Defendants represented to the FDA and in the product labeling that the Filshie Clip had a migration rate of only 0.13% (Dkt. #123-3; #137-1).

2. Defendants later became aware of studies showing migration rates as high as 25% or higher (Dkt. #123-5; Dkt. #123-6).

3. Despite this knowledge, Defendants did not update their labeling or adequately inform the FDA about this significant discrepancy (Dkt. #123-4 ¶ 6).

4. Defendants received numerous complaints about symptoms related to the device's migration but determined that the reporting threshold was not met as to any of them. (Dkt. #137-3 at p. 21-24).

Ms. Bulox and Ms. Merlo have met the requirements set forth in the *Schouest* case and in doing so have established that their failure to warn claims survive preemption. The Report

improperly ignores instructive jurisprudence in reaching the opposite conclusion. For these reasons, the Court should deny Defendants' Motions for Summary Judgment.

## IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court reject the Magistrate Judge's Report and Recommendation and deny Defendants' motions for summary judgment (Dkt. #123, #124, #125).

Dated: March 17, 2025

Respectfully submitted,

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## CERTIFICATE OF WORD COUNT

The undersigned certifies that, pursuant to the Rules of this Court, the instant filing, which was prepared using Times New Roman 12-point typeface, contains 4,024 words, excluding the parts of the document that are exempted by this Court's rules. This certificate was prepared in reliance on the word-count function of the word-processing system (Microsoft Word) used to prepare the document.

*/s/ Simon B. Purnell*
Simon B. Purnell

**CERTIFICATE OF SERVICE**

The undersigned certifies that on this 17th day of March, 2025, a true and correct copy of the foregoing document was served on all known counsel of record in accordance with the Federal Rules of Civil Procedure.

*/s/ Simon B. Purnell*
Simon B. Purnell